

the functional activity i.e., the heparin-binding properties and/or the capability of sulfated polysaccharides to inhibit erythrocyte agglutination by 28 kDa purified heparin-sepharose chromatography fraction. No amino acid sequence is provided and the monoclonal antibodies used are neither defined nor characterized.

Claims 56-67 make reference to a particular sequence, SEQ ID NO:19. No such sequence is taught by the abstract and the Examiner has not provided evidence as to why such would be inherent in the teachings of the reference. Thus the rejection of the claims as anticipated is not well founded.

Further, nothing in the abstract would allow one skilled in the art to identify and/or characterize this HBHA antigen, for the following reasons:

i) The monoclonal antibodies used to identify the 28 kDa protein are not characterized and/or named. Thus, an artisan would not find sufficient the information provided to identify the 28 kDa protein. Although one skilled in the art is informed that 28 kDa protein is different from the fibronectin-binding protein of antigen 85 complex, sufficient information is not provided to permit one to identify the 28 kDa protein.

ii) The experimental conditions of the chromatography used are not described in the citation. Indeed, heparin-sepharose chromatography may lead to other surface proteins, such as the laminin-binding protein (LBP), which have the same molecular weight as HBHA but which do not function in the adhesion of mycobacteria to epithelial cells via binding to heparin sulfate receptors. Consequently, an artisan could not distinguish LBP and HBHA in fractions obtained from heparin-sepharose chromatography. Pathogenic mycobacteria produce LBP and HBHA to interact with host cells suggesting that mycobacteria have developed several means of cell interactions, increasing the difficulty in clearly distinguishing these two proteins having an apparent molecular weight of 28 kDa.

In view of the above it will be clear that the citation neither teaches nor would have suggested the claimed invention.

On page 2 of the Action, the Examiner states the rejection of claims 56-67 under 35 USC 112, second paragraph, has been withdrawn. Thus, the statement in item (10) on page 3 of the Action is believed to be the result of a clerical error. Clarification of the record is requested.

This application is submitted to be in condition for allowance and a Notice to that effect is requested.

Respectfully submitted,

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